

## LeSiever® Sterilizing-grade Capsule Filters with Hydrophobic PVDF

LePure designs, develops, manufactures and services high-quality filtration, fluid processing systems, and single use products worldwide. LeSiever® Sterilizing-grade Capsule Filters contain an hydrophilic PVDF (Polyvinylidene fluoride) membrane that offers the greatest assurance of filtration performance, stability and service life for sterilization, prefiltration and clarification of low to high-contaminant liquids. Sterile filtration is very important in the drug production and is implemented for bacterial removal throughout bioprocessing to achieve bioburden control.



LeSiever® Sterilizing-grade Capsule Filters can be used for applications requiring the highest degree of sterility assurance. They are easy scale up from laboratory, pilot plant and production applications, including filtration of cell and tissue culture media, microbiological growth media, additives, parenteral solutions, buffer preparations, plasma proteins, serum, vaccines and pharmaceutical water et al.

### Typical applications

LeSiever® Sterilizing-grade Capsule Filters offer high quality filtration in a wide variety of applications.

- Cell and tissue culture media
- Media additives
- Biological solutions
- Parenteral solutions
- Serum
- Protein solutions
- process intermediates
- Virus suspensions
- Buffers

### Specification

LeSiever® Sterilizing-grade hydrophilic PVDF capsule filters are available in double layer 0.45/0.2  $\mu\text{m}$  and single layer 0.2  $\mu\text{m}$  hydrophilic PVDF membrane, and multiple configurations that vary by filtration area and type of inlet/outlet connection.

#### ○ LeSiever® Sterilizing-grade Capsule Filter with 0.45/0.2, 0.2/0.2 $\mu\text{m}$ Hydrophilic PVDF

For double layer filters, they are the final 0.2  $\mu\text{m}$  membrane layer which ensures sterility of the filtrate, while pre-filter layer can significantly improve the capacity of the filter. 0.45 and 0.2  $\mu\text{m}$  heterogeneous double layer sterilizing hydrophilic PVDF membrane can be used for plasma proteins, serum, vaccines and process intermediates.

#### ○ LeSiever® Sterilizing-grade Capsule Filters with 0.2 $\mu\text{m}$ Hydrophilic PVDF

0.2  $\mu\text{m}$  single layer sterilizing hydrophilic PVDF membrane is particle-free liquids such as buffer, cell and tissue culture media, media additives, pharmaceutical water.

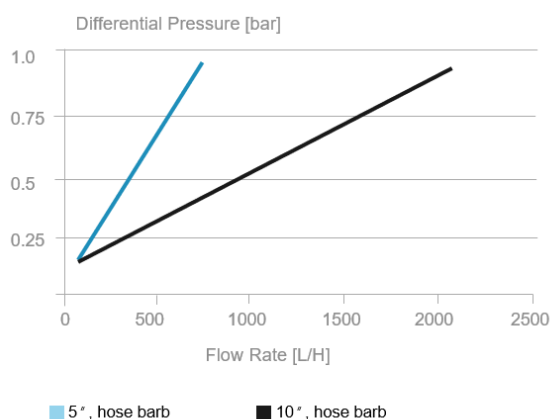
### Advantage

- Sterilizing grade hydrophilic PVDF membrane
- Low proteins binding and extractable
- Broad chemical compatibility
- High flow rates at low pressure drops
- Provide double layer format and single layer format
- 100% integrity tested during manufacture
- Available with a variety of connectors

## Technical specification

Size	Size 1	Size 5	2"	4"	5"	10"	20"
Filtration Area m <sup>2</sup>   ft <sup>2</sup>	0.018   0.19	0.055   0.59	0.13   1.4	0.23   2.5	0.33   3.6	0.66   7.1	1.32   14.2
Pore size (µm)	0.2, 0.45/0.2						
Materials of Construction							
Filter media	Polyvinylidene Fluoride (PVDF)						
Structural components	Polypropylene						
O-ring	Silicone (SI)						
Supports	Polypropylene						
Maximum Pressure							
Forward mbar (psi) at 23°C	4000 (58)	5000 (73)	5000 (73)	5000 (73)	5000 (73)	5000 (73)	5000 (73)
Reverse mbar (psi) at 23°C	2000 (29)	2500 (36)	2500 (36)	2500 (36)	2500 (36)	2500 (36)	2500 (36)
Integrity Test							
Diffusion Test @ 2400 mbar  34.8 psi, mL/min	≤1.8	≤4	≤5.4	≤8.6	≤12	≤20	≤42
Bubble Point, at 23 °C, mbar (psi)	≥3000 (43.5)/≥3200 (46.5)						
Bacterial Retention	Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> Brevundimonas diminuta (ATCC® 19146) per ASTM® F838-83 methodology						
Toxicity	Meet the requirements of USP 88						
TOC/Conductivity	Effluent meets the WFI criteria for USP <643>, Total Organic Carbon, and USP <645>, Conductivity, after a WFI water flush of: 5.5 L at 25 °C and 10 L at 25 °C						
Oxidizable Substances	Effluent meets the requirements for USP Sterile Water for Injection after a water flush of: 1000 mL.						
Bacterial Endotoxins	Aqueous extraction contains ≤0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test						
Gravimetric Extractables	≤1.0 mg in 70/30 % IPA/water						
Sterilization							
gamma compatible format	Gamma irradiation 25-40 kGy						
autoclavable format	5 autoclave cycles of 60 min @ 126 °C						
Non-Fiber Releasing	Component materials meet the "non-fiber releasing" criteria as defined in 21 CFR 210.3 (b) (6).						
Component Material Toxicity	Component materials meet the criteria of the USP <87>, USP <88>						

## Standard Flow Rate versus Pressure Drop



Flow rates for 0.2 µm capsule filter

## Ordering information

### LeSiever® Sterilizing-grade Capsule Filters

<b>N</b>	<b>P</b>	<b>1</b>	<b>D</b>	<b>5</b>	<b>D</b>	<b>0 5</b>	<b>T T</b>	<b>1</b>
Territory	Product Code	Product type	Membrane Material	Pore Size	Sterilization	Size	Inlet/Outlet	Packaging
N: International --: China	P: Liquid filter	1: Capsule filter	D: Hydrophilic PVDF	1: 0.2 µm 5: 0.45/0.2 µm J: 0.2/0.2 µm	D: Gamma compatible A: Autoclavable S: sterile (gamma irradiated)	S1: 180cm <sup>2</sup> S5: 550cm <sup>2</sup> 02: 2inch 04: 4inch 05: 5inch 10: 10inch 20: 20inch	T: 3/2" (38.1mm) Tri-Clamp F: 3/4" (19.1mm) Tri-Clamp H: 1/2" (12.7mm) Hose Barb B: 3/4" (19.1mm) Hose Barb O: 1/4" (6.4mm) Hose Barb	1: 1/pack 3: 3/pack 4: 4/pack 6: 6/pack M=Manufacture

Size	0.2 µm	0.45/0.2 µm	0.2/0.2 µm	Filtration Area	Package
S1	P1D1DS1--6	P1D5DS1--6	P1DJDS1--6	180cm <sup>2</sup>	6/pack
S1	P1D1AS1--6	P1D5AS1--6	P1DJAS1--6	180cm <sup>2</sup>	6/pack
S1	P1D1SS1--6	P1D5SS1--6	P1DJSS1--6	180cm <sup>2</sup>	6/pack
S5	P1D1DS5--4	P1D5DS5--4	P1DJDS5--4	550cm <sup>2</sup>	4/pack
S5	P1D1AS5--4	P1D5AS5--4	P1DJAS5--4	550cm <sup>2</sup>	4/pack
S5	P1D1SS5--4	P1D5SS5--4	P1DJSS5--4	550cm <sup>2</sup>	4/pack
2inch	P1D1D02--4	P1D5D02--4	P1DJD02--4	0.13m <sup>2</sup>	4/pack
2inch	P1D1A02--4	P1D5A02--4	P1DJA02--4	0.13m <sup>2</sup>	4/pack
2inch	P1D1S02--4	P1D5S02--4	P1DJS02--4	0.13m <sup>2</sup>	4/pack
4inch	P1D1D04--3	P1D5D04--3	P1DJD04--3	0.23m <sup>2</sup>	3/pack
4inch	P1D1A04--3	P1D5A04--3	P1DJA04--3	0.23m <sup>2</sup>	3/pack
4inch	P1D1S04--3	P1D5S04--3	P1DJS04--3	0.23m <sup>2</sup>	3/pack
5inch	P1D1D05--1	P1D5D05--1	P1DJD05--1	0.33m <sup>2</sup>	1/pack
5inch	P1D1A05--1	P1D5A05--1	P1DJA05--1	0.33m <sup>2</sup>	1/pack
5inch	P1D1S05--1	P1D5S05--1	P1DJS05--1	0.33m <sup>2</sup>	1/pack
10inch	P1D1D10--1	P1D5D10--1	P1DJD10--1	0.66m <sup>2</sup>	1/pack
10inch	P1D1P10--1	P1D5P10--1	P1DJP10--1	0.66m <sup>2</sup>	1/pack
10inch	P1D1S10--1	P1D5S10--1	P1DJS10--1	0.66m <sup>2</sup>	1/pack
20inch	P1D1D20--1	P1D5D20--1	P1DJD20--1	1.32m <sup>2</sup>	1/pack
20inch	P1D1A20--1	P1D5A20--1	P1DJA20--1	1.32m <sup>2</sup>	1/pack
20inch	P1D1S20--1	P1D5S20--1	P1DJS20--1	1.32m <sup>2</sup>	1/pack

--Inlet/Outlet:

H = 12.7 mm 1/2" Hose Barb

B = 19.1 mm 3/4" Hose Barb (Only 20")

F = 19.1 mm 3/4" Tri-Clamp (Size 1 Only)

O = 6.4 mm 1/4" Hose Barb (Size 1 Only)

\*Packaging:

1 = 1/pack (5", 10", 20")

3 = 3/pack (4")

4 = 4/pack (2")

6 = 6/pack (Size 1)

